Krystal Biotech Announces United Kingdom MHRA Approval of VYJUVEK® for the Treatment of Dystrophic Epidermolysis Bullosa

May 18, 2026

VYJUVEK approved for the treatment of DEB from birth with flexible administration options similar to those already granted in the United States, European Union, and Japan

VYJUVEK is the first genetic medicine approved in the United Kingdom for the treatment of DEB

PITTSBURGH, May 18, 2026 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS) today announced that, on May 15, 2026, the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) granted marketing authorization to VYJUVEK® (beremagene geperpavec-svdt) for the treatment of wounds in patients with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (*COL7A1*) gene, from birth.

VYJUVEK is the first genetic medicine approved in the United Kingdom for the treatment of DEB and is designed to address the root cause of the disease by delivering functional copies of the human *COL7A1* gene to provide wound healing and sustained functional type VII collagen protein expression with redosing. The approval in the United Kingdom also includes flexible administration options similar to those granted in the United States, European Union, and Japan, allowing for dosing at home or in a healthcare setting, with the option for administration by patients or their caregivers.

"This latest approval brings VYJUVEK closer to patients in the United Kingdom and advances our vision of providing corrective therapy to as many DEB patients as possible," said Laurent Goux, Executive Vice President, Head of International at Krystal Biotech. "We are now focused on close collaboration with relevant authorities to support broad and rapid access across the United Kingdom."

VYJUVEK also fulfilled the United Kingdom Orphan Designation criteria and will be added to the Orphan Register held by the MHRA, allowing it to benefit from up to 12 years of market exclusivity.

The approval of VYJUVEK by the MHRA was based on a comprehensive clinical dataset including results from the Company's Phase 1/2 GEM-1 and Phase 3 GEM-3 studies, which collectively provided clear clinical evidence of successful *COL7A1* gene delivery and durable wound closure following topical administration, and was further supported by results from the Company's open label extension study and real-world experience with VYJUVEK.

The timing for launch of VYJUVEK in the United Kingdom will depend on completion of reimbursement procedures currently underway.

"We are delighted that VYJUVEK is now approved in the United Kingdom as the first and only corrective therapy for the treatment of DEB," said Suma Krishnan, President of Research and Development at Krystal Biotech. "This positive decision by the MHRA, our fourth approval following the United States, European Union, and Japan, reflects both the strength of our clinical dataset and our commitment to maximizing access to VYJUVEK worldwide."

VYJUVEK was previously approved by the Food and Drug Administration in the United States in May 2023, the European Commission in April 2025, and Japan's Ministry of Health, Labour and Welfare in July 2025.

UNITED KINGDOM INDICATION
VYJUVEK is indicated for the treatment of wounds in patients with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (*COL7A1*) gene, from birth.

About Krystal Biotech, Inc.
Krystal Biotech, Inc. (NASDAQ: KRYS) is a fully integrated, commercial-stage, global biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs. VYJUVEK®, the Company's first commercial product, is the first-ever redosable gene therapy and the first genetic medicine approved in the United States, Europe, and Japan for the treatment of dystrophic epidermolysis bullosa. The Company is rapidly advancing a robust preclinical and clinical pipeline of investigational genetic medicines. Krystal Biotech is headquartered in Pittsburgh, Pennsylvania. Visit www.krystalbio.com to learn more or follow us on LinkedIn and X.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements regarding the timing of the launch of, and access to, VYJUVEK in the United Kingdom, and the completion of related reimbursement procedures; the potential duration of orphan market exclusivity in the United Kingdom; and the Company's commitment to maximizing access to VYJUVEK worldwide. Words such as "anticipate," "believe," "expect," "intend," "plan," "will," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based on the Company's current expectations and are subject to risks and uncertainties that could cause actual results to differ materially, including risks related to reimbursement for VYJUVEK; uncertainties associated with the maintenance of orphan designation and exclusivity in the United Kingdom; commercial and competitive risks; and such other important factors as are set forth under the caption "Risk Factors" in the Company's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q filed with the U.S. Securities and Exchange Commission. The Company undertakes no obligation to update any forward-looking statements except as required by law.

CONTACT
Investors and Media:
Stéphane Paquette, PhD
Krystal Biotech

spaquette@krystalbio.com

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